

**Tennessee Medical Laboratory Board Meeting**  
**October 15, 2009**  
**Minutes**

**Date:** October 15, 2009

**Time:** 9:00 CDT

**Location:** Bureau of Health Licensure and Regulation  
TN Department of Health  
Heritage Place Iris Room  
227 French Landing, Ground Floor  
Nashville, TN 37243

**Members Present:** Norman Crowe, Chairman, Independent Lab Manager  
Edward McDonald, MD Pathologist, Vice-Chairman  
Trudy Papuchis, MD Pathologist Hospital Administrator  
Cheryl Arnott, S.A.-Cytotechnologist  
Gloria Jenkins, Citizen Representative  
Diane Robbins, Medical Technologist  
Christopher H. Seay, Medical Technologist  
Darius Y. Wilson, MAT, Ed.D. Educator  
Delores Voigt, MT Hospital Administrator

**Members Absent:** Pamela Bullock, M.D., Non-educator Pathologist  
Steven R. Dickerson, M.D., Non Pathologist Physician  
Annie Washington, Medical Technologist

Pathologist Educator Member (Position Vacant)

**Staff Present:** Lynda S. England, Medical Technologist Consultant,  
Director  
Jerry A. Gowen, Medical Technologist Consultant  
Alison Cleaves, Deputy General Counsel, Advisory  
Attorney  
Elizabeth Miller, Director-Health Related Boards  
Julia Daniels, Medical Technologist Consultant/  
Surveyor, East Tennessee Regional Office  
Taylor Carpenter, Medical Technologist  
Consultant/Surveyor, East Tennessee Regional Office  
Karon Hathcoat, Medical Technologist Consultant/  
Surveyor, West Tennessee Regional Office  
Onezean Otey, Jr., Medical Technologist  
Consultant/Surveyor, Middle Tennessee Regional Office  
Mary Hamblen, Medical Technologist  
Consultant/Surveyor, West Tennessee Regional Office

**Staff Absent:** None

**CLIA Representative:** Sandra Bogard, CLIA Manager

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Quorum:**

A sufficient number of board members were present to constitute a quorum

**Call To Order:**

The meeting was called to order at 9:05am CDT by Mr. Crowe.

**Presiding Officer:**

The meeting was conducted by Mr. Crowe

**Introductions:**

Mr. Crowe asked that the board members introduce themselves to the audience and state the interest group they represented

**New Board Member:**

One (1) new board appointee was introduced to the audience other board members.

Ms. Cheryl Arnott, was appointed to the seat formerly held by Ms. Alison McDonald-Spakes whose term expired this year. Ms. Arnott represents the cytotechnologist category of licensure and represents the middle Tennessee sector.

**New Staff Member:**

Mr. Jerry A. Gowen was introduced to the board members and audience. Mr. Gowen is the technologist consultant and serves as the board's administrative assistant working in health related boards.

**New Attorney:**

Ms. Allison Cleaves, Attorney. Ms. Beagley, Board Attorney is on leave.

**Conflict of Interest Policy:**

Ms. Cleaves introduced herself to the audience and board members. Board members were reminded by Ms. Cleaves to recuse themselves from any discussion or vote pertaining to meeting business if the subject material would have any relativity to board member business or any decision that would appear to be a conflict of interest.

**Approve Minutes:**

**P & E**

A motion to approve the July 15, 2009 Personnel & Education Committee minutes was made by: Dr. McDonald.  
Second: Mr. Seay.

Motion approved

**Board**

The minutes from the July 16, 2009 board meeting were approved on a motion made by: Mr. Seay.

Second: Dr. McDonald.

Motion approved

**Board Reports:**

**P&E Committee Minutes**

Dr. Wilson presented a report on the actions of the Board's Personnel & Education Committee meeting, October 14, 2009.

Motion: Mr. Seay.

Second: Ms. Robbins.

The report was approved as given.

**Contested Cases**

No contested cases were presented during this meeting.

**Consent, Agreed,  
Compliance Orders**

**Consent**

Mr. Seay and Ms. Voight recused themselves.

The consent order was reviewed by the Board.

Donna Gookin  
Memphis, TN 38107  
Medical Laboratory Technologist  
License # 11925

The board unanimously voted to revoke this license via a consent order presented by Attorney Cleaves. Ms. Gookin failed to comply with a monitoring agreement through TNPAP.

Motion to accept: Dr. McDonald

Second: Dr. Papuchis

Motion approved

**Agreed**

There were no agreed orders presented during this meeting

**Compliance**

There were no compliance orders presented during this meeting.

**Letters of  
Reprimand**

There were no letters of reprimand presented during this meeting.

**Tennessee Professional**

The report was given by Ms. Elaine Eaton representing

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**Peer Assistance Program**  
**(TNPAP):**

Mike Harkreader, MA, RN \* TNPAP State Director.

The TNPAP statistical report for the period July 1, 2009 to September 18, 2009 stated this advocacy agency was currently monitoring six (6) individuals.

During this period there were two (2) referrals, One individual was determined to need a monitoring agreement. A monitoring agreement was entered into but has since been referred to the Department of Health for review.

The second individual referred was evaluated and it was determined that they did not need a monitoring agreement.

The referral history included one (1) individual having a history of arrest or drug related arrest/DUI.

The second individual was referred for a forgery issue. Both individuals were referred to TNPAP from the medical laboratory board.

Four (4) individuals were discharged from TNPAP with two (2) individuals successfully completing the monitoring program.

Motion to accept this report: Ms. Voigt.  
Second: Mr. Seay.

Report Approved.

*Note: Review of TNPAP materials via internet counts as clock hours toward continuing education credits. A certificate of completion documenting review of these materials can be completed at the end of the internet session. Internet site: [www.TNPAP.org](http://www.TNPAP.org)*

**Rules/Rulemaking**  
Alison Cleaves, Board Attorney

No rule-making hearing was conducted during this meeting.

**Ratifications:** The following items were presented to board members for ratification per staff, state surveyor or facility request:

**Exemptions for point of care testing procedures**

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**(POCT) in a licensed  
facility (See Attachment 1).**

**Maury Regional  
Hospital**

Amy Bridges, POC Coordinator for Maury Regional Hospital, requested modification to existing exemption granted July 13, 2006, for Licensed Registered Nurses to perform and report blood gasses, electrolytes, glucose, BUN, creatinine, hematorcrit and ionized calcium facility wide using the I-Stat system.

Motion to approve: Dr. McDonald

Second: Ms. Robbins

Motion approved

**Indian Path  
Hospital**

Karen Cox, MSHA Point of Care Coordinator, requested Licensed Registered Nurses to perform and report Troponin I testing procedures on the I-Stat in the emergency department.

Motion to approve: Dr. McDonald

Second: Ms. Voight

Motion approved

**Wellmont  
Hancock,  
Sneadville**

Richard Doyle, POC Coordinator for Wellmont Health Systems, requested an extension to their existing exemption to allow Registered Nurses, Licensed Practical Nurses, Respiratory Therapists, Radiology Technicians and Emergency Medical Technicians to perform and report sodium, potassium, chloride, total carbon dioxide, ionized calcium, glucose, BUN, lactate, hematocrit and calculated hemoglobin on the I-Stat, in the Emergency Department.

Motion to approve: Dr. McDonald

Second: Mr. Seay

Motion approved

**Direct More Than Three (3) Labs  
Rule 1200-6-3-.13(5) Medical  
Lab Facilities:**

No requests were presented to the Board during the meeting.

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Discuss, Review and Take  
Action (If Needed)**

**Necessity of  
Licensure:  
Clarksville  
Physician  
Services (Dover  
Medical Clinic in  
Stewart County)**

WTRO surveyor, Mary Hamblen, and Paul Miller, Director of Physician's Practices for Gateway Medical Center, were available to discuss the possible need for licensure for this facility.

Discussion followed regarding the structure, ownership and employees of the clinic.

Rule 1200-06-03-.16 (2)(a) was referenced regarding ownership and was the reason for questioning ownership, thus the need for licensure.

Motion to accept as a POL, thus no license needed:

Dr. McDonald

Second: Mr. Seay

Motion Approved

**Genome  
Explorations**

There was no one present from Genome Explorations to address questions of the Board. The question was is whether or not a license for this facility is needed.

Genome Explorations was strictly research and military application, however they are exploring expansion of their practice to include providing testing to the general population in patient care.

Motion to require licensure on the information presented if moving into the clinical diagnostic and treatment area:  
Dr. McDonald

Second: Ms. Voight

Motion approved

**POL  
Interpretation  
Karon Hathcoat,  
WTRO Surveyor**

Discussion centered around a laboratory recently surveyed that is located in Tennessee, however the providers are from Kentucky, holding clinic in the state, performing CBC's and an occasional urine HCG and all other testing is taken back to Kentucky and performed in their lab their or sent to a reference laboratory.

The rules for a collection station were discussed.

Mr. Crowe stated that the first and foremost question is

whether they are a POL and that would determine any further questions. This item was discussed. Different scenarios were explored.

This discussion was for clarification and no motion was necessary. The entity meets the definition of a POL.

A ten (10) minute break was called by the chair.

The meeting was called back into order by Board Chairman, Mr. Crowe

**National Registry of  
Certified Chemists**

Ms. England reported that a request from this body was made to the office requesting that they be considered as a credentialing agency for Chemistry director.

Moved that NRCC be accepted as a qualifying agency:  
Dr. Papuchis

Second: Dr. McDonald

There was further discussion about whether or not to include other laboratory personnel other than the director's level. It was agreed that other special analyst personnel credentialed by the NRCC would be included.

Motion approved.

**Revisit FISH  
(Fluorescence in  
situ hybridization)**

No action except for a discussion regarding the possible addition of a Molecular specialist on the Board. The Board needs the input of a person knowledgeable in this area for guidance and to act as a consultant. A new Board position representing this discipline would be ideal.

If a person(s) knowledgeable in FISH, and who is/are willing to consult with the Board on issues related to that discipline, can be found, they are invited to attend the Board meeting and address the body. A teleconference with suitable person(s) would be appropriate, also. General guidelines could be developed for further interaction with the TMLB.

Mr. Crowe will follow-up on this project and take the lead in it's development.

**Criminal  
Background  
Policy**

Board members revisited the policy adopted October 2007 concerning Criminal Background Checks.

The revised policy reads:

“All applicants seeking licensure as Medical Laboratory Personnel are required to submit to a criminal background check as a prerequisite to licensure. The applicant shall submit to a FBI/TBI fingerprint scan through the State of Tennessee’s approved vendor or its equivalent as determined by the Board. The results of the criminal background check must be submitted directly from the vendor identified in the Board’s licensure application materials to the Board’s office (Tenn Comp R and Regs Rule 1200-06-01-.05 (1)(m). In the event that an applicant’s criminal background check cannot be performed because the applicant’s fingerprints are unreadable, then the applicant’s criminal background check will be performed based on the applicant’s name and social security number.”

Adopted by the Tennessee Medical Laboratory Board on the 15th of October, 2009.

Motion to adopt policy: Dr. McDonald.  
Second: Dr. Wilson.

The policy was approved as written

**Health Services  
Administration  
Amendment  
Deletion**

Representatives Present Were:

Mary Kennedy, Deputy General Counsel For HSA  
John R. Dunn, DVM, PhD, TN. Dept of Health  
David Smalley, PhD, Director, TN Laboratory Services

The discussion was an amendment deletion concerning 1200-06-03-.12 (1) & (2) Rules and Regulations Governing Medical Laboratories, rules set out in 1200-14-01-.02 for Health Services Administration (HSA).

This rule change would establish a more comprehensive review of reportable communicable and environmental diseases agents to DOH. Rules would be more nimble and responsive as pathogens in the environment change.

The Health Services Administration would be responsible for the composition and maintenance of this report.



Laboratory rules and regulations would continue to delegate the responsibility of the medical laboratory director to follow the guidelines established in this rule change.

Mr. Crowe requested General Counsel draft revision language to 1200-06-03-.12, Reportable Diseases, to reference the new rule under the public health.

Motion to delete present rule 1200-06-03-.12 and insert the new rule language consistent with the DOH's revised rule and maintaining the responsibility stated in item one (1): Dr. Papuchis  
Second: Dr. Wilson

Motion approved.

## **Waived Test Menu**

### **Influenza A & B**

Members discussed the addition of Influenza A & B screens to the test menu for health fairs and health screens in response to concern of mass testing events for the H1N1 swine flu virus.

After discussion, board members agreed to take no action but to defer to any emergency declaration issued by state or federal entities concerning testing.

### **Add all CLIA waived tests and instruments to State Menu**

Amy Bridges, Point of Care Coordinator Maury Regional Hospital, Columbia, TN., withdrew request at this time.

## **Board Director's Report**

Ms. England gave the report which included administrative office activities performed during the past quarter.

The director's report is on file in the administrative office.

Motion to accept Director's report as presented:  
Mr. Seay.  
Second: Dr. McDonald.

Report: Approved.

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The chair called for a ten (10) minute break at 11:50 AM

The meeting was called back into order at Noon (12PM) by Board Chairman, Mr. Crowe

**Reinstatement of License:** No request for the reinstatement of a facility license was presented for review during the meeting.

**OGC Report** Alison Cleaves, Interim Advisory Attorney, did not give a report during this meeting

**Bureau of Investigations (BIV)** Investigative Report July-September 2009

**Report**

**Juanita Stone: Disciplinary Coordinator**

The following actions were reported to board members:

New Complaints: Zero (0)

Closed Complaints: Zero (0)

Closed-Letter of Warning: Zero (0)

Closed-Letter of Concern: (0)

Closed No Action: Zero (0)

Closed-Referred to OGC: Zero (0)

Pending Court Action: (0)

Currently Opened Complaints: Ten (10)

Allegation: Unprofessional Conduct: Zero (0)

Unlicensed Practice: Zero (0)

Other: Zero (0)

All complaints must go through the Bureau of Investigations for review before they are closed or referred to the Office of General Counsel.

Motion to Accept Report: Ms. Jenkins.

Second: Mr. Seay.

The report was accepted as read

**Reports/Discussion Regional Surveyors**

**ETRO Report**

East TN Regional Office: Julia Daniels

Unsatisfactory/ Unsuccessful Proficiency Testing:

The East Tennessee Regional Office reported zero (0) unsuccessful proficiency testing for the third quarter of 2009. (Two out of Three PT Events or Two in a Row)

Complaint Investigations:

The East Tennessee Regional Office conducted zero (0) investigation(s) during the last quarter.

**MTRO Report**

Middle TN Regional Office: Onezean Otey, Jr.

Unsatisfactory/Unsuccessful Proficiency Testing:

The number of licensed laboratories demonstrating a first occurrence of unsuccessful proficiency testing events (two of three events): one (1).

Licensed laboratories with a second occurrence of unsuccessful proficiency testing events (three out of four or three in a row): zero (0).

Complaint Investigation:

The Middle Tennessee Regional Office conducted zero (0) complaint investigation(s) during this quarter.

**WTRO Report**

West Tennessee Regional Office: Karon Hathcoat

Unsatisfactory /Unsuccessful Proficiency Testing:

There were zero (0) labs in this region that had an unsatisfactory or unsuccessful proficiency testing events during this quarter.

Complaint Investigations:

There was zero (0) complaint investigations conducted during the past quarter.

Motion to approve Surveyor's Reports: Mr. Seay.  
Second: Ms. Arnott.

Surveyor's Reports: Approved

**Board Ratification of  
Laboratory Initial License**

Mr. Crowe recused himself from the discussion on Lab Corp  
Gavel was passed to Dr. McDonald, Vice Chairman

**Laboratory  
Corporation of  
America**

Medical Laboratory Director: Jere W. Ferguson, M.D.  
Anatomic/Clinical Pathology  
Category: Independent Laboratory  
Specialties: Hematology, Clinical Chemistry, and Urinalysis  
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**271 Medical Park  
Blvd.  
  
Bristol, TN 37620**

Surveyor: Julia Daniels, Consultant II  
East TN Regional Office

Motion to approve License: Dr, Papuchis.  
Second: Ms. Jenkins.

License Approved

**Tennessee  
Reproductive  
Laboratory  
  
6031 Shallowford  
Road  
  
Chattanooga, TN  
37421**

Medical Laboratory Director: Paul A. Kaplan, D.O..  
Anatomic/Clinical Path

Category: Independent Laboratory  
Specialties: Hematology, pH (body fluid)

Surveyor: Julia Daniels, Consultant II  
East TN Regional Office

Motion to approve License: Dr. McDonald.  
Second: Ms. Voigt.

License Approved.

**Med South Medical  
Center  
1700 Woodlawn  
Avenue  
  
Dyersburg, TN 38024**

Medical Laboratory Director: Mark Burton, M.D.  
Anatomic/Clinical Pathology Hematology

Category: Independent Laboratory  
Specialties: Bacteriology, Parasitology, Virology, General  
Immunology, Clinical Chemistry, Urinalysis, and  
Hematology.

Surveyor: Karen Hathcoat, Consultant I  
West TN Regional Office

Motion to approve License: Dr. McDonald  
Second: Mr. Seay.

License Approved.

**Review License Eligibility for  
Medical Laboratory Director:**

**Ludmila D.  
Matyakhina, Ph.D.  
Rockville, MD  
Director: Clinical  
Cytogenetics**

Motion to approve application: Dr. McDonald.  
Second: Mr. Seay

Application Approved

**Sallyanne Fossey,  
Ph.D.  
Hendersonville, TN  
Director:  
Histocompatibility &  
Immunogenetics**

Motion to approve application: Dr. McDonald.  
Second: Ms. Jenkins

Application Approved.

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**Stuart C. Bogema,  
Ph.D.  
Collierville, TN  
Director: Toxicology**

Motion to approve application: Dr. McDonald  
Second: Dr. Papuchis

Application Approved.

**Neil B. Quigley, Ph.D.  
Knoxville, TN  
Director: Molecular  
Diagnostics**

Motion to approve application: Dr. McDonald  
Second: Dr. Papuchis

Application Approved

Mr. Crowe recused himself from the discussion of Xiao-Ziang Zhang, Ph.D  
Gavel passed to Dr. McDonald, Vice Chairman:

**Xiao-Ziang Zhang,  
Ph.D.  
Brentwood, TN  
Director: Molecular  
Diagnostics**

Motion to approve application: Dr. Papuchis  
Second: Mr. Seay

Application Approved

Gavel passed to Mr. Crowe, Chairman

**Other Business**

Mr. Allen Robinson's application for licensure, previously denied, was represented to the Board for consideration under Rule 1200-06-01-.22 (1)(a)(2)(i).

Mr. Robinson was requested to appear before the Board.

Motion to reconsider Mr. Robinson's application and to table: Dr. McDonald  
Second: Mr. Seay

Motion approved

There was discussion regarding what direction to take regarding competency, work experience, initial training, etc.. Mr. Crowe requested Ms. Cleaves to investigate what language other boards use to address the situation as presented and to come back at the next meeting with suggested direction.

**Statement of Next Meeting**

The next Board Meeting will be January 14, 2010, and will begin at 9 AM CST in the Iris Room, Ground Floor, Heritage Place, 227 French Landing, Metro Center, Nashville, TN. 37243.

**Record of Adjournment**

With no further business to discuss, the meeting was adjourned at 1:30 PM CDT on a motion properly presented by Dr. McDonald, seconded by Mr. Seay.